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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 1 of 1

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| Application Number | 10/715,548 |
| Filing Date | November 19, 2003 |
| First Named Inventor | Edward M. Sellers |
| Art Unit | 2681 |
| Examiner Name | Moise, Emmanuel Lionel |
| Attorney Docket Number | 10251-49 |

U.S. PATENT DOCUMENTS

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Signature

/Donna Jagoe/ (05/17/2007)

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| Application Number | 10/715,548 |
| Filing Date | November 19, 2003 |
| First Named Inventor | E. SELLER et al. |
| Group Art Unit | Unassigned |
| Examiner Name | Unassigned |
| Attorney Docket Number | 62805.000040 |

U.S. PATENT DOCUMENTS

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| /DJ/ | 1. | 5653987 | | Modi et al. | 08-1997 | |
| /DJ/ | 2. | 5760049 | | Viner | 06-1998 | |

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|---------------------|-----------------------|-------------------------|---------------------|-----------------------------------|---|---|----------------|
| | | Office ³ | Number ⁴ | Kind Code ⁵ (if known) | | | |
| /DJ/ | 3. | WO | 95/34679 | | 12/1995 | | |
| /DJ/ | 4. | SU | 1803032 A1 | | 03/1993 | | |

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

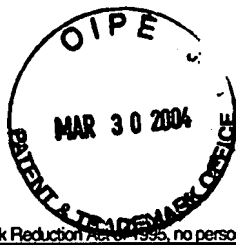
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|---------------------|-----------------------|---|----------------|
| /DJ/ | 5. | NAKAJIMA, M et al., Characterization of CYP2A6 involved in 3'-hydroxylation of cotinine in human liver microsomes, J. Pharmacol. Exp. Therap., (1996), Vol. 277, No. 2, pp. 1010-1015 | |
| /DJ/ | 6. | NAKAJIMA, M. et al., Role of human cytochrome P450A6 in C-oxidation of nicotine, Drug Metabol. Disp. (1996), Vol. 24, No. 11, pp. 1212-1217 | |
| /DJ/ | 7. | TSUJIMOTO, A. et al., Potent inhibitory action of pilocarpine on hepatic drug metabolism, Jpn. J. Pharmacol., (1972) Vol. 22, No. 5, 736 | |

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Sheet 2 of 2

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| Filing Date | November 19, 2003 |
| First Named Inventor | E. SELLER et al. |
| Group Art Unit | Unassigned |
| Examiner Name | Unassigned |
| Attorney Docket Number | 62805.000040 |

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|------------------------|--------------------------|---|----------------|
| /DJ/ | 8. | FOTH, H. et al., Nicotine metabolism in isolated perfused lung and liver of phenobarbital- and benzoflavone-treated rats, Arch. Toxicol., (1991) Vol. 65, No. 1, pp. 68-72 | |
| | 9. | KYEREMATEN, G. A. et al., Metabolism of nicotine by hepatocytes, Biochem. Pharmacol., (1990) Vol., No. 8, pp. 1747-1756 | |
| | 10. | YAMAZAKI, H. et al., Cytochrome P450 sE1 and 2A6 enzymes as major catalysts for metabolic activation of nitrosodialkylamines and tobacco-related nitrosamines in human liver microsomes, Carcinogenesis (1992) Vol. 13, No. 10, pp. 1789-1794 | |
| | 11. | CAPLUS, DN 120:138085, Gamitskij et al., SU 1803032 A1, 1993/03/23, english abstract with notes from oral translation | |
| | 12. | MAYS et al., Methoxsalen is potent inhibitor of caffeine in humans, Clin. Pharmacol. Ther., 42:621-626 (1987) | |
| | 13. | MAENPAA et al., Biochem. Pharmacol., 48(7), (1994), 1363-9 | |
| /DJ/ | 14. | BENOWITZ, N. L. et al., Deficient c-oxidation of nicotine, Clinical Pharmacology and Therapeutics, 57(5): 590-594 (1995) (Abstract) | |
| | 15. | Copy of International Search Report dated June 6, 1999 | |

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/Donna Jagoe/ (05/17/2007)

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